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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
JOIKE, MICHELE K	
ART UNIT	PAPER NUMBER
1636	
MAIL DATE	DELIVERY MODE
11/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/606,302	PORRO ET AL.	
	Examiner	Art Unit	
	MICHELE K. JOIKE	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-10 and 15-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-9,15,16,18,20 and 28-33* is/are rejected.

7)☒ Claim(s) *10, 17, 19, 21-27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed August 13, 2008. Claims 7-10 and 15-33 are pending and under consideration in the instant application.

Any rejection of record in the previous Office Action, mailed May 13, 2008 that is not addressed in this action has been withdrawn. Because this Office Action introduces new rejections other than those set forth in the previous Office Action, and are not necessitated by amendment, this Office Action is **Non-Final**.

The declaration under 37 CFR 1.132 filed August 13, 2008 is sufficient to overcome the rejection of claims 7-10 based upon lack of enablement under 35 USC 112(1). However, the specification is objected to for not containing the date, accession number and sufficient description of the deposited materials. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear to what the yield is being compared. 35% greater than what?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7-9, 15, 16, 18, 20 and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hancock et al in view of Ostergaard et al.

Hancock et al (IDS reference C10, see entire reference) teach a method of generating ascorbic acid comprising obtaining a *Saccharomyces cerevisiae* yeast capable of converting an ascorbic acid precursor into L-ascorbic acid (L-AA), culturing the yeast in a medium comprising an ascorbic acid precursor and isolating the ascorbic acid. Hancock et al teach this method wherein the ascorbic acid precursor is selected from L-galacto-1,4-lactone, L-gulono-1,4-lactone or L-galactose. The authors suggest that the cells produce ascorbic acid using enzymes from its D-EAA biosynthetic

pathway, for example D-arabinose dehydrogenase or D-arabino-1,4-lactone oxidase. Support for this hypothesis is shown by the finding that pre-loading the cells with D-arabinose results in a marked reduction of L-AA production, because the D-arabinose stimulates production of D-EAA instead. They show that these enzymes can produce L-ascorbic acid because of their broad substrate specificity, so if the proper precursors are added to the medium, L-AA will be made instead of D-EAA. Since these enzymes are endogenous to yeast, they have a promoter active in yeast. They teach such a method wherein the yeast accumulates ascorbic acid in the medium at levels greater than background (see Table 1) and wherein the isolating step comprises lysing the cells, centrifuging them, and performing HPLC analysis. However, they do not teach transforming the cells with D-arabinose dehydrogenase, D-arabino-1,4-lactone oxidase or L-guluno-1,4-lactone oxidase.

Ostergaard et al (Micro. and Molecular Biol. Rev. 64(1): 34-50, 2000, especially pp. 34, 46) teach that *S. cerevisiae* is an attractive organism to transform because it is nonpathogenic, is susceptible to genetic modifications by recombinant DNA technology. The ease of transforming *S. cerevisiae* makes this organism a good host for protein production. Transforming an organism allows for scale-up production of desired proteins.

A person of ordinary skill in the art, upon reading Hancock et al, would have recognized the desirability of using D-arabinose dehydrogenase or D-arabino-1,4-lactone oxidase to produce L-AA because recombinant yeast is being used for the production of L-AA, and these enzymes naturally occur in yeast. It would have been

obvious to one of ordinary skill in the art at the time the invention was made to choose from a finite number of enzymes with a reasonable expectation of success of producing L-AA. Hancock et al teach that an endogenous D-arabinose dehydrogenase or D-arabino-1,4-lactone oxidase is capable of producing L-AA, therefore one of ordinary skill in the art would have a reasonable expectation of success in using a transformed D-arabinose dehydrogenase or D-arabino-1,4-lactone oxidase in *S. cerevisiae* because Ostergaard et al teach that *S. cerevisiae* is an attractive organism to transform because it has a multicomponent pathway and is capable of performing posttranslational modifications.

Allowable Subject Matter

Claims 10, 17, 19, and 21-27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE K. JOIKE whose telephone number is (571)272-5915. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele K. Joike
Examiner
Art Unit 1636

/David Guzo/
Primary Examiner
Art Unit 1636